

## **REMARKS**

Applicant appreciates the detailed examination evidenced by the Official Action mailed February 6, 2007 (hereinafter "the Action"). In response, Applicant has amended the Application as follows:

Independent Claims 21, 27, 36, 56, 62, 72, 91, 92, 98 and 107 have been amended to clarify that the electrodes are internally implanted electrodes applied to the heart.

In view of the above amendments and the comments that follow, Applicant respectfully submits that all claims are in condition for allowance.

### **I. The rejections to Claims 62-67 and 71 under § 112 have been overcome**

Claims 62-67 and 71 stand rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. The Action takes the position that the application does not disclose a system that comprises all three of the following: means for determining a refractory period associated with the heart using premature stimulation, means for determining an activation recovery interval measurement associated with the heart, and means for determining a Monophasic activation potential (MAP) reading of the heart. Applicants submit that support for such amendments can be found, for example, on page 11, lines 20-26, which discusses that various techniques can be used to determine which regions are likely to contain the fastest activating region of the heart. Applicants note the use of the plural for of the term "techniques" and submit that the original disclosure is clear that one or more of the techniques can be used. However, Claim 62 has been amended to clarify that the system includes at least one of the techniques.

For at least these reasons, Applicants submit that the rejections under § 112 have been overcome and request that such rejections be withdrawn.

**II. The § 102 Rejections: Claims 21-32, 36, 55-61, 72, 92-103 and 106-107 are patentable over U.S. Patent Publication No. 2001/0056289 to Sippensgroenewegen ("Sippensgroenewegen").**

Claims 21-32, 36, 55-61, 72, 92-103 and 106-107 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sippensgroenewegen.

**A. Independent Claims 21, 27, 36, 56, 62, 72, 92 and 107**

Claim 21 recites a method for reducing an occurrence of fibrillation of a heart, including:

detecting a premature contraction of the heart for a plurality of heart beats characterized by nonsustained tachycardia; and

applying an electric stimulus to a region of the heart that is likely to contain a fastest activating region, wherein a location of the fastest activating region is determined by:

inducing fibrillation of the heart; and

determining, using internally implanted electrodes applied to the heart, at least one of a monophasic activation potential (MAP) reading associated with the fibrillating heart, a refractory period associated with the heart using premature stimulation, and a power spectrum analysis to provide a spectrum with a peak power at a highest frequency.

Independent Claims 27, 36, 56, 62, 72, 92 and 107 include recitations similar to the above-underlined portions of Claim 21.

The Action concedes that Sippensgroenewegen does not disclose that the fastest one activating region is determined by determining a refractory period or by determining an activation recovery interval measurement. *See* the Action, page 5. However, the Action takes the position that Sippensgroenewegen discloses "determining a monophasic activation potential reading (MAP) associated with the fibrillating heart (see Sippensgroenewegen page 1, paragraph 7, page 5, paragraphs 51 and pages 6-8). Applicants respectfully disagree.

The activation of cardiac cells results from the movement of ions across the cell membrane, which causes a transient depolarization or activation potential. A monophasic activation potential (MAP) reading typically involves using internally implanted electrodes applied to the heart to obtain intracellular recordings of the

activation potential. Internally implanted electrodes applied to the heart are illustrated, for example, in Figure 5 of the current application. Claims 21, 27, 36, 56, 62, 72, 92 and 107 have been amended to clarify that internally implanted electrodes applied to the heart are used to determine a monophasic activation potential (MAP), a refractory period and/or a power spectrum analysis.

In contrast, Sippensgroenewegen relies on an external array 10 of sensors 12 distributed across anterior and posterior skin surfaces of the patient to provide multi-lead electrocardiogram (ECG) data at a plurality of locations. See Sippensgroenewegen, paragraphs 40. Applicants submit that Sippensgroenewegen does not teach or suggest a monophasic activation potential (MAP) as maintained in the Action, which cites page 1, paragraph 7, page 5, paragraphs 51 and pages 6-8 of Sippensgroenewegen. The cited portions of Sippensgroenewegen merely discuss external ECG systems that are applied to the body surface.

Notably, Sippensgroenewegen make no mention of monophasic activation potentials. The external ECG systems of Sippensgroenewegen are used to determine an arrhythmogenic region using an apparently complex procedure that involves arranging integral values within a data matrix according to the locations at which the signals are sensed along the body surface. The data matrix is graphically plotted and compared to a database having a plurality of known arrhythmia cycles with associated known arrhythmogenic regions for each known arrhythmia cycle. See Sippensgroenewegen, paragraph 16. The signals discussed in Sippensgroenewegen are simply not monophasic activation potentials as can clearly be seen in the multiphase signals, for example, in Figures 1B, 3A-3D.

Moreover, Sippensgroenewegen teaches away from using internally implanted electrodes applied to the heart. Sippensgroenewegen discusses that its non-invasive techniques avoid "massively invasive simultaneous intracardiac sensor techniques" (Abstract, paragraph 14) and that, "[p]referably, heart cycle signals are sent while no intracardiac probe is present in the heart" (emphasis added)(paragraph 16).

Applicants note that determining the arrhythmogenic region in Sippensgroenewegen is used to position catheters for ablation therapy, which are typically removed after ablation. Therefore, there are no reasons to modify Sippensgroenewegen to use

internally implanted electrodes applied to the heart as recited in Claims 21, 27, 36, 56, 62, 72, 92 and 107.

Accordingly, Sippensgroenewegen does not teach or suggest all of the recitations of Claims 21, 27, 36, 56, 62, 72, 92 and 107 as required by Section 102. For at least these reasons, Applicants submit that independent Claims 21, 27, 36, 56, 62, 72, 92 and 107 and Claims 20, 22-26, 28-32, 56-61, 63-67, 71, 93-97 depending therefrom are patentable over the cited art. Applicants respectfully request that the rejections of such claims under Section 102 be withdrawn.

**B. Independent Claims 55 and 98**

Claim 55 recites a system for reducing an occurrence of fibrillation of a heart, including:

means for detecting a premature contraction of the heart for a plurality of heart beats characterized by nonsustained tachycardia using internally implanted electrodes applied to the heart; and

means for applying an electrical stimulus to a region of the heart not in fibrillation determined to contain a fastest activating region.

Claim 98 recites a computer program product for reducing an occurrence of fibrillation of a heart, including:

a computer readable medium having computer readable program code embodied therein, the computer readable program code comprising:

computer readable program code configured to apply, during heart activity detected by internally implanted electrodes applied to the heart characterized by at least one of normal heartbeat activity, premature heartbeat activity, or nonsustained tachycardia activity, an electrical stimulus to a region of the heart not in fibrillation determined to contain a fastest activating region.

As discussed above, Sippensgroenewegen proposes measuring ECG signals from the body surface and does not teach or suggest detecting heart activity using internally implanted electrodes applied to the heart. In fact, Sippensgroenewegen teaches away from using internally implanted electrodes applied to the heart for its ablation therapy

positioning techniques because Sippensgroenewegen discusses repeatedly that its non-invasive techniques avoid "massively invasive simultaneous intracardiac sensor techniques" (Abstract, paragraph 14) and that, "[p]referably, heart cycle signals are sent while no intracardiac probe is present in the heart" (emphasis added)(paragraph 16). Therefore, there are no reasons to modify Sippensgroenewegen to use internally implanted electrodes applied to the heart as recited in Claims 55 and 98.

For at least these reasons, Applicants submit that independent Claims 55 and 98 and Claims 99-106 depending therefrom are patentable over the cited art. Accordingly, Applicants respectfully request that the rejections of such claims under Section 102 be withdrawn.

### **III. The § 103 Rejections**

#### **A. Claims 104-105 are patentable over Sippensgroenewegen.**

Claims 104-105 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sippensgroenewegen. Claims 104-105 depend from Claim 98 and are patentable at least per the patentability of Claim 98 as discussed above. In addition, Claims 104-105 are patentable for the reasons that follow.

The Action concedes that Sippensgroenewegen does not disclose that the fastest activating region is determined by a refractory period (Claim 104) or by determining an activation recovery interval (Claim 105). The Action takes the position that it would have been an obvious matter of design choice to modify Sippensgroenewegen to include these features as an apparent substitution for the MAP technique, which the Action alleges is taught by Sippensgroenewegen.

As discussed with respect to the rejections under § 102 above, Sippensgroenewegen does not teach or suggest using monophasic activation potentials (MAP). Instead, Sippensgroenewegen uses multiphasic ECG signals, which are arranged in a data matrix according to locations at which the signals are sensed and ultimately compared to a database of known arrhythmia cycles with associated known arrhythmogenic regions. Accordingly, Applicants submit that

Sippensgroenewegen also does not teach or suggest the use of refractory periods or activation recovery intervals.

For at least these reasons, Claims 104-105 are separately patentable, and Applicants respectfully request an indication of same.

**B. Claims 20 and 91 are patentable over Sippensgroenewegen in view of U.S. Patent No. 7,123,954 to Narayan ("Narayan").**

Claims 20 and 91 were rejected in the Action under 35 U.S.C. § 103(a) as being unpatentable over Sippensgroenewegen in view of Narayan.

Claim 20 depends from Claim 21 and is patentable at least per the patentability of Claim 21 discussed above.

Independent Claim 91 recites a computer program product for reducing an occurrence of fibrillation of a heart, including:

a computer readable medium having computer readable program code embodied therein, the computer readable program code comprising:

computer readable program code configured to detect a premature contraction of the heart for a plurality of heart beats characterized by nonsustained tachycardia using internally implanted electrodes applied to the heart; and

computer readable program code configured to apply a defibrillation stimulus to a region of the heart not in fibrillation determined to contain a fastest activating region.

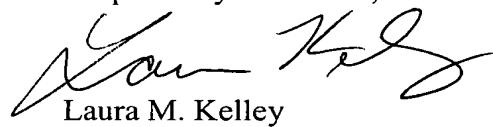
As discussed above, Sippensgroenewegen does not teach or suggest internally implanted electrodes applied to the heart. Narayan likewise proposes the use of external ECG signals (see, *e.g.*, Figure 1). Furthermore, Sippensgroenewegen teaches away from using internally implanted electrodes applied to the heart during its ablation therapy positioning techniques because Sippensgroenewegen proposes that non-invasive ECG techniques avoid "massively invasive simultaneous intracardiac sensor techniques" (Abstract, paragraph 14) and that, "[p]referably, heart cycle signals are sent while no intracardiac probe is present in the heart" (emphasis added)(paragraph 16). Therefore, there are no reasons to modify Sippensgroenewegen to use internally implanted electrodes applied to the heart as recited in Claim 91.

For at least these reasons, Applicants submit that Claims 20 and 91 are patentable over Sippensgroenewegen and Narayan. Applicants respectfully request that the rejection of Claims 20 and 91 under Section 103 be withdrawn.

**CONCLUSION**

Accordingly, Applicant respectfully submits that all objections/rejections to the pending claims have been overcome and respectfully requests a Notice of Allowance in due course. If any informal matters arise, the Examiner is encouraged to contact the undersigned by telephone at (919) 854-1400.

Respectfully submitted,

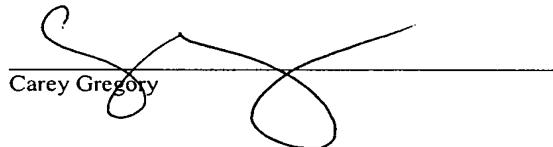


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